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TO : ART UNIT: 1642

COMPANY : UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. SERIAL NO. : 10/554,181

FAX NO. : 571-273-8300

FROM : ALBERT WAI-KIT CHAN/jh

RE : NALDINI, ET AL., FOR LENTIVIRAL VECTORS CARRYING SYNTHETIC BI-DIRECTIONAL PROMOTERS AND USES THEREOF", U.S. SERIAL NO. 10/554,181 FILED OCTOBER 21, 2005, CORRESPONDING TO INTERNATIONAL APPLICATION NO. PCT/US04/000227, FILED APRIL 21, 2004, CLAIMING THE BENEFIT OF U.S. SERIAL NO. 60/465,080, FILED APRIL 24, 2003 - OUR DKT. #1130-PCT-US

TOTAL NUMBER OF PAGES, INCLUDING COVER SHEET: 18DATE: DECEMBER 5, 2006

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT for NALDINI, et al., for LENTIVIRAL VECTORS CARRYING SYNTHETIC BI-DIRECTIONAL PROMOTERS AND USES THEREOF, U.S. Serial No. 10/554,181, Filed October 21, 2005 including Exhibit A (3 pages) and Exhibit 1 (9 pages)

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<u>Albert Wai-Kit Chan</u>	<u>12/5/06</u>
Albert Wai-Kit Chan	Date
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : NALDINI, et al.

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U.S. Serial No. : 10/554,181

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Filed : October 21, 2005

For : LENTIVIRAL VECTORS CARRYING SYNTHETIC BI-DIRECTIONAL PROMOTERS AND USES THEREOF

Law Offices of Albert Wai-Kit Chan, LLC  
World Plaza, Suite 604  
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December 5, 2006

Mail Stop Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, Applicants would like to direct the Examiner's attention to the following references which are listed below and on Forms PTO/SB/08A and PTO/SB/08B (which are attached hereto as Exhibit A), and reference #8 is further attached as Exhibit 1.

1. International Publication Number WO9712622 for THE SALK INSTITUTE FOR BIOLOGICAL STUDIES, Published April 10, 1997, "Vector and Method of Use for Nucleic Acid Delivery to Non-Dividing Cells"
2. International Publication Number WO9931251 for CELL GENESYS, INC., Published June 24, 1999, "Method and Means for Producing High Titer, Safe, Recombinant Lentivirus Vectors"

Applicants : NALDINI, et al.  
U.S. Serial No.: 10/554,181  
Filed : October 21, 2005  
Page : 2

3. International Publication Number WO0029421 for CELL GENESYS, INC., Published May 25, 2000, "Selection System for Generating Efficient Packaging Cells for Lentiviral Vectors"
4. International Publication Number WO0066759 for CELL GENESYS, INC., Published November 9, 2000, "Method and Means for Producing High Titer, Safe, Recombinant Lentivirus Vectors"
5. International Publication Number WO9930742 for Naldini, et al., Published June 24, 1999, "Therapeutic Use of Lentiviral Vectors"
6. International Publication Number WO0029557 for CELL GENESYS, INC., Published May 25, 2000, "A Sensitive Screening System for Envelope-Defective Recombinant Virus"
7. International Publication Number WO0189580 for VLAAMS INTERUNIVERSITAIR INSTITUUT VOOR BIOTECHNOLOGIE VZW, Published November 29, 2001, "Systemic and Cardiovascular Transduction With Lentiviral Vectors"
8. AMENDOLA, et al., "Coordinate dual-gene transgenesis by lentiviral vectors carrying synthetic bidirectional promoters", Nature Biotechnology, Vol. 23, No. 1, Pages 108-116 (January 2005) [Exhibit 1]

Copies of the above International Patents are on file at WIPO; therefore, a copy will not be provided. Applicants' attorney's office may be contacted in the event that the Examiner would like a copy of the reference.

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned

Applicants : NALDINI, et al.  
U.S. Serial No.: 10/554,181  
Filed : October 21, 2005  
Page : 3

attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

Albert Wai-Kit Chan

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Substitute for Form 1449/PTO		Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>		Application Number	10/554,181
		Filing Date	October 21, 2005
		First Named Inventor	Luigi Naldini
		Art Unit	1642
		Examiner Name	Not Yet Known
		Attorney Docket Number	1130-PCT-US
Sheet 1	of 3		

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cito No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T#
		Country Code <sup>2</sup> "Number" "Kind Code" <sup>3</sup> (if known)				
1	WO9712622		4-10-1997	THE SALA INSTITUTE FOR BIOLOGICAL STUDIES		
2	WO9931251		6-24-1999	CELL GENESYS, INC.		
3	WO0029421		5-25-2000	CELL GENESYS INC.		
4	WO0066759		11-9-2000	CELL GENESYS INC.		
5	WO9930742		6-24-1999	NALDINI et al.		
6	WO0029557		5-25-2000	CELL GENESYS INC.		

Examiner Signature		Date Considered	
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**\*EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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Sheet 12	Page 3	
		Application Number 10/554,181
		Filing Date October 21, 2005
		First Named Inventor Luigi Naldini
		Art Unit 1642
		Examiner Name Not Yet Known
		Attorney Docket Number 1130-PCT-US

FOREIGN PATENT DOCUMENTS					
Examiner initials*	Cite No.*	Foreign Patent Document Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear
	7	WO0189580	11-29-2001	VLAAMS INTERUNIVERSITAIR INSTITUUT VOOR BIOTECHNOLOGIE VZW	

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				Examiner Name	Not Yet Known
Sheet	3	of	3	Attorney Docket Number	
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#### **OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS**

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